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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/596,303

01/26/2007

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EXAMINER

WALKER, AMANDA H

ART UNIT

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NOTIFICATION DATE

DELIVERY MODE

04/15/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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pto@gbpatent.com

Office Action Summary	Application No. 10/596,303	Applicant(s) MATSUZAKI ET AL.	
	Examiner AMANDA H. WALKER	Art Unit 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 10-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 10-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 June 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10-29-07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

Claims 1-8 and 10-21 are pending. Claim 9 is cancelled. Claims 1, 4, 6, 8, 10 and 21 are amended.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is directed to a polyhedral pellet including a pair of opposite, non-parallel surfaces. Claim 7 is directed to a trihedral shaped pellet. The definition of trihedral is as follows:

- having or formed by three planes meeting at a point

Therefore the trihedral shaped pellet cannot have a pair of opposite surfaces since they all touch one another.

In addition, a cylindrical (claim 8) cannot form a trihedral shape, since there are not three planes.

Claim Rejections - 35 USC § 102/ 35 USC § 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8 and 10-21 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hiraide (JP 2003-135583) as evidenced by Mohri et al. (United States Patent Number 6159441). A machine translation was obtained from the Japanese Patent Office website and was attached in the previous rejection. References refer to the machine translation.

Regarding Claim 1: Hiraide et al. teaches a bone replacement material 100 (FIG. 2/representative figure) that is a pellet shaped and defined by a plurality of surfaces. The material has a porosity of less than 75% (para. 0022). Despite its participation in a “complex”, the calcium-phosphate particle 100 can be still be described as a pellet. This appears to have a plurality of surfaces including a pair of opposite non-parallel surfaces that are angled with respect to each other (see representative drawing/figure 2). The fact that it is a part of a complex does not keep it from being a pellet.

Considering that the figure and method of making the complex and pellet of Hiraide et al. appears to teach all of the claimed structure, the other claimed limitations either inherent or implicit (MPEP 2112.01 I). When the reference discloses all the limitations of a claim except a property or function, and the examiner cannot determine whether or not the reference inherently possesses properties which anticipate or render

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obvious the claimed invention but has basis for shifting the burden of proof to applicant as in *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980). See MPEP §§ 2112-2112.02.

Regarding Claims 2-8 and 14: The pellets 100 taught by Hiraide et al. appear to have roughly prismatic shapes (FIG. 2/representative figure). Hexahedral/rectangular, pentahedral/triangular, and trihedral or cylindrical (FIG. 2/representative figure) formations, if not inherent, are types of polyhedrals that would have been within the level of one of ordinary skill in the art depending upon the particular application for the pellets. Mohri et al. is an example of a more complex polyhedral and absent any showing of criticality to the preferred shapes, forming four, five, or six sided polyhedrals would have been obvious to one skilled in the art based upon ordinary capabilities of one skilled in the art. Furthermore, the limitation "subjected to chamfering processing" does not further define the structure of the pellet.

Regarding Claim 10: Hiraide et al. teaches that each polyhedral pellet is either inherently or implicitly defined by a plurality of surfaces. The pellets inherently or implicitly include pairs of opposite surfaces that are inclined with respect to each other, at a predetermined angle (FIG. 2/representative figure). The figure inherently or implicitly indicates that the surfaces are inclined at angles that would fall between 10-60 degrees.

Regarding Claims 11-13: Hiraide et al. teaches that the diameters of each pellet 100 average between 0.0001-10 mm (para 0012). Therefore, it is submitted that at least one of the pellets will inherently or implicitly have a longest edge between 5-10 mm and a shortest edge between 2-5 mm. The volume would therefore inherently or implicitly be between 13-239 mm³.

Regarding Claims 15 and 16: The manner in which the pellets taught by Hiraide et al. are used does not, in itself, serve to further define the structure of the pellet. The pellets are *capable of* being packed into a cavity with a variety of different types of tools.

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Regarding Claims 17-19: Hiraide et al. teaches that the material is a calcium phosphate based compound with a Ca/P ratio of 1-2 (para 0012).

Regarding Claims 20 and 21: The manner in which the pellets taught by Hiraide et al. are used does not, in itself, serve to further define the structure of the pellet. Furthermore, the pellets and complex taught by Hiraide et al. are *capable of* being packed into a cavity with a variety of different tools, in a variety of different anatomical areas.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-21 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 7,238,209 (referred to as '209 herein) in view of Hiraide et al.

Regarding Claim 1: Claim 1 of '209 teaches a bone replacement material to be packed into a bone defect, wherein the material is formed into a pellet. The pellet is defined by a

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plurality of surfaces including a pair of opposite, *non-adjointed* (non-parallel) surfaces inclined at a predetermined angle, and thus has a *roughly* polyhedral shape. However, Claim 1 of '209 does not teach that the material has a porosity of $\leq 75\%$.

Hiraide et al. teaches a bone replacement material 100 (FIG. 2/representative figure) that is a pellet shaped and defined by a plurality of surfaces. The material has a porosity of less than 75% (para. 0022). Claim 1 of '209 and Hiraide et al. are combinable because they are from the same field of endeavor, namely, bone implant materials. At the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the pellet taught by Claim 1 of '209 with the porosity of Hiraide et al., and one would have been motivated to do so to ensure that cells could infiltrate the material.

Regarding Claim 10: Claim 2 of '209 teaches that the angle is in the range of 10-60 degrees.

Regarding Claim 11: Claim 3 of '209 teaches that the longest edge is between 5-10 mm.

Regarding Claim 12: Claim 4 of '209 teaches that the length of the shortest edge is in the range of 2-5 mm.

Regarding Claim 13: Claim 5 of '209 teaches that the volume is in the range of 13-239 mm³.

Regarding Claim 14: Claim 6 of '209 teaches that the material has been subjected to chamfering.

Regarding Claims 15 and 16: Claim 7 of '209 teaches that the pellets are adapted to be packed into the vertebral body and are aggregated therein. Furthermore, the manner in which the pellets taught by Claim 7 of '209 are used does not, in itself, serve to further define the structure of the pellet. The pellets are *capable* of being packed into a cavity with a variety of different types of tools.

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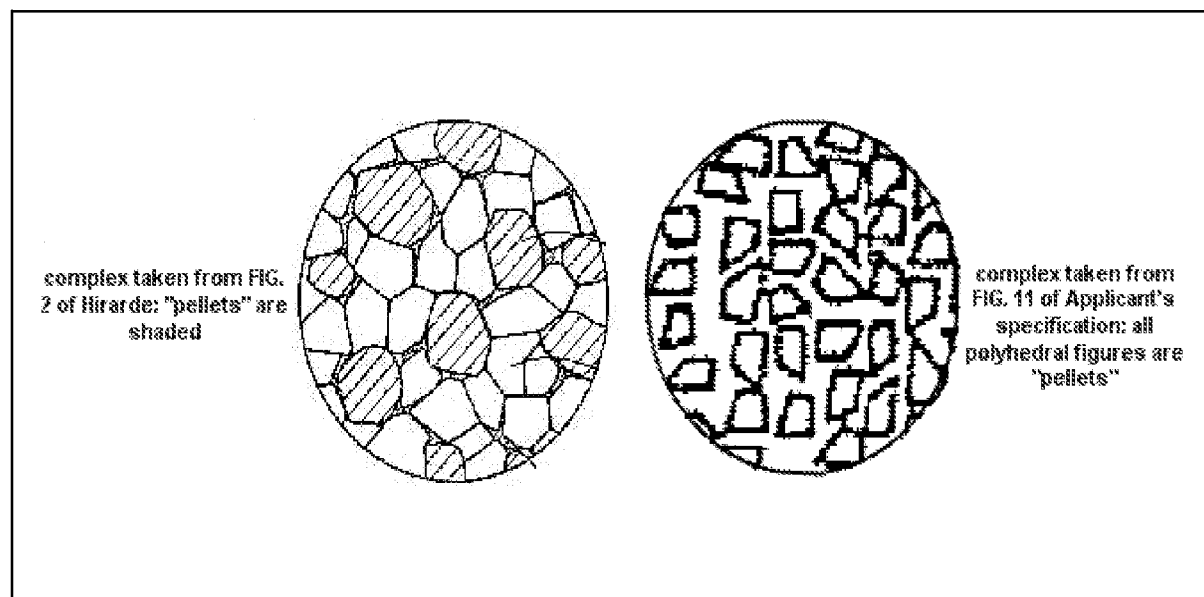
Regarding Claims 17-19: Claims 8-10 of '209 teaches that the replacement is a calcium phosphate based ceramic with a Ca/P ratio of 1-2.

Regarding Claims 20-21: Claims 1 and 11 of '209 teaches that the pellets are capable of being packed into a cavity using a variety of types of tools, and that each pellet has an inclined surface that faces the inclined surface of an adjacent pellet. The pellets, when ejected, go in multiple directions. Furthermore, the manner in which the pellets taught by claims 1 and 11 of '209 are used does not, in itself, serve to further define the structure of the pellet. The apparatus used in the process of inserting the pellets also does not serve to further define the structure of the pellets.

Response to Arguments

Applicant's arguments filed 2-1-08 have been fully considered but they are not persuasive.

In response to applicant's argument that particles/pellets 100 taught by Hiraide et al. are components of a complex and not comparable to the pellet recited in the pending claims (paragraphs 1 and 3 on page 7), a recitation of the intended use of the claimed invention must



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result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The fact that the particles/pellets 100 are in conjunction with other materials when placed into the body is not a difference that merits patentable weight based on Applicant's claim language. Furthermore, it is noted that a collection of Applicant's "pellets" within a vertebra could also be considered a "complex". See added figure above for clarification.

Applicant also argues that Hiraide et al. does not teach a pair of opposite non-parallel surfaces defining the complex (page 8, para. 1). However, the claim refers to a pellet with a plurality of surfaces including a pair of opposite non-parallel surfaces, not a complex, which is taught by Hiraide et al. (100 of FIG. 2/representative figure).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMANDA H. WALKER whose telephone number is (571)270-3296. The examiner can normally be reached on 8-5, M-Th, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on (571) 272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AHW
4-2-08

/DAVID J ISABELLA/
Supervisory Patent Examiner, Art Unit 4156